

d.) Remarks.

Applicant has amended the specification to insert the claim made for priority on the inventorship declaration, canceled (claims 20-25) or otherwise amended the withdrawn claims (claims 15, 16, 18, 19, 21-24 and 28-30), added new claims 31-40, and amended claims 1, 4, 14-19 and 28-30. Support for the new claims and the amendments can be found throughout the specification. For example, support for the amendments to claim 1 can be found in original claim 4 and also the specification at paragraph 97. The amendment to claim 4 can be found in the specification at paragraphs 82-100. The amendment to claim 17 incorporate the recited aspects of claim 4 and also claims 15 and 18. The amendments to claims 28-30 deleted the withdrawn aspects and added aspects of the invention as set forth in the specification at paragraph 42. Support for new claims 31-41 can be found in the existing claims and also throughout the specification, such as paragraphs 82-100. No new matter or new issues are raised with these amendments and their entry is respectfully requested. Currently claims 1-19 and 24-41 are pending.

Remarks Regarding 35 U.S.C. § 112, Second Paragraph

Claims 17 and 20 stand rejected, under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for being dependent on non-elected claims. Applicant has amended claims 17 and 20 to be presented in independent form thus rendering the rejection moot.

Remarks Regarding 35 U.S.C. § 112, First Paragraph

A. Claims 1-14, 17, 20, and 25-27 stand rejected, under 35 U.S.C. § 112, first paragraph, for allegedly not being enabled by the specification. Applicant respectfully traverses this rejection.

According to the Office Action, the specification is enabling for an isolated peptide as in SEQ ID NOs 1-3 and 5, wherein the nonapeptide consists of up to three fatty acids that are selected from the group consisting of stearic acid, arachidic acid and arachadonic acid, but is not enabling for any isolated peptide comprising SEQ ID NOs 1, 2, 3 or 5.

Applicant respectfully disagrees. The sequence information provided is fully enabling to those of ordinary skill in the art. Further, each of the dependant claims recite additional aspects that would not encompass any isolated peptide with the stated sequence. For example, claims 2 and 3, respectively, recite that there must be an arginine at the amino terminus and a phenylalanine at the carboxy terminus. The claims further recite that the peptide further comprise a plurality of fatty acids (claim 4), wherein at least one is an unsaturated fatty acid (claim 5), wherein each fatty acid is selected from the group consisting of stearic acid, arachidic acid, arachadonic acid and combinations thereof (claim 6), wherein the peptide is a nonapeptide (claim 7), wherein certain amino acids are derivatized (claim 9) or serine and phenylalanine (claim 10, or a serine-O-fatty acid ester (claim 11), and claim 13 which includes all of the stated limitations the Examiner believes to be enabled.

Nevertheless, and solely to expedite prosecution, Applicant has amended claim 1 to incorporate the recited aspects of claim 4 (that the claimed isolated peptide comprises a plurality of fatty acids), and also that the claimed peptide, when administered to a patient, increases the effective innate immune system response of that patient (see specification, paragraph 87).

Thus, the rejection of claims 1-14, 17, 20, and 25-27, under 35 U.S.C. § 112, first paragraph, is overcome and Applicant respectfully requests that it be withdrawn.

B. Claims 1-14, 17, 20 and 25-27 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly not being described by the specification. Applicant respectfully traverses this rejection.

According to the Office Action, the specification provides an adequate written description for an isolated peptide as in SEQ ID NOs 1-3 and 5, wherein the nonapeptide consists of up to three fatty acids that are selected from the group consisting of stearic acid, arachidic acid and arachadonic acid, but is not sufficient for any isolated peptide comprising SEQ ID NOs 1, 2, 3 or 5.

Applicant respectfully disagrees. The sequence information provided is fully descriptive to those of ordinary skill in the art from a complete reading of the specification including the claims. Further, each of the dependant claims recite additional aspects that would not encompass any isolated peptide with the stated sequence. For example, claims 2

and 3, respectively, recite that there must be an arginine at the amino terminus and a phenylalanine at the carboxy terminus. The claims further recite that the peptide further comprise a plurality of fatty acids (claim 4), wherein at least one if an unsaturated fatty acid (claim 5), wherein each fatty acid is selected from the group consisting of stearic acid, arachidic acid, arachadonic acid and combinations thereof (claim 6), wherein the peptide is a nonapeptide (claim 7), wherein certain amino acids are derivatized (claim 9) or serine and phenylalanine (claim 10, or a serine-O-fatty acid ester (claim 11), and claim 13 which includes all of the stated limitations the Examiner believes to be otherwise described.

Nevertheless, and solely to expedite prosecution, Applicant has amended claim 1 to incorporate the recited aspects of claim 4 (that the claimed isolated peptide comprises a plurality of fatty acids), and also that the claimed peptide, when administered to a patient, increases the effective innate immune system response of that patient (see specification, paragraph 87).

All of the pending claims are described in the specification in full compliance with the Revised Interim Guidelines for the Examination of Patent Applications under 35 U.S.C. § 112, first paragraph (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday, January 5, 2001). As set forth in these guidelines, "an adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention" (page 1105). On page 1106, the guidelines further state that:

"Factors to be considered in determining whether there is sufficient evidence of possession include... partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function... Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient."

Applicant respectfully asserts that the sequence information provided is fully descriptive to those of ordinary skill in the art from a complete reading of the specification including the claims, and in full compliance with the guidelines. In addition, the

incorporation the fatty acid aspects of claim 4 into the independent claims of this application at the very least provide the partial structure, properties and characteristics of the present invention, as required. The guidelines are further satisfied by the recited function of increasing patients' effective innate immune system response, coupled with the above-mentioned structural characteristics.

Thus, for all the reasons set forth above, the rejection of claims 1-14, 17, 20, and 25-27, under 35 U.S.C. § 112, first paragraph, is overcome and Applicant respectfully requests that it be withdrawn.

Remarks Regarding 35 U.S.C. § 102(b)

A. Claims 1, 7, 17, 20 and 25-27 stand rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Publication No. 2002/0165123A1 (the "123 Publication").

Applicant respectfully traverses this rejection.

B. Claims 1, 7, 17, 20 and 25-27 stand rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 6,875,738 (the "738 Patent"). Applicant respectfully traverses this rejection.

C. Claims 1, 7, 17, 20 and 25-27 stand rejected, under 35 U.S.C. § 102(b), as allegedly anticipated by U.S. Patent No. 6,946,445 (the "445 Patent"). Applicant respectfully traverses this rejection.

Solely to expedite prosecution, Applicant has amended the claims to include the recited aspects of claim 4, an unrejected claim, into each independent claim. Applicant respectfully asserts that a peptide having one or more fatty acids is not disclosed or suggested in any of the cited references. In addition, Applicant has further amended independent claims to recite that the composition increases the innate immune response when administered to a patient. None of the peptides of the cited reference disclose or suggest a peptide that increases innate immune response. For at least these reasons, as specifically recited in the claims, the claims are not disclosed or suggested in any of the cited references.

Applicant respectfully requests that the rejection of claims 1, 7, 17, 20 and 25-27, under 35 U.S.C. § 102(b), with regard to the 123 Publication, the 738 patent and the 445 Patent be withdrawn as moot.

Conclusion

In view of the foregoing amendments and/or remarks, reconsideration of the application and issuance of a Notice of Allowance is respectfully requested. If there are any issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the number below.

Should additional fees be necessary in connection with the filing of this Responsive Amendment, or if a petition for extension of time is required for timely acceptance of same, the Commissioner is hereby authorized to charge **Deposit Account No. 14-1437, referencing Attorney Docket No. 8109.005US, for any such fees**; and Applicant hereby petitions for any needed extension of time not otherwise accounted for with this submission.

Respectfully submitted,
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